



January 7, 2022

EKOS Corporation
Jocelyn Kersten
Vice President, Regulatory & Clinical Affairs
11911 N Creek Parkway South
Bothell, Washington 98011

Re: K063620
Trade/Device Name: EKOS Micro-Infusion System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Jocelyn Kersten:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 6, 2007. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W.
O'Connell -S

Digitally signed by
Gregory W. O'Connell -
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Date: 2022.01.07
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Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



AUG 6 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

EKOS Corporation
c/o Ms. Jocelyn Kersten
Vice President, Regulatory and Clinical Affairs
11911 North Creek Parkway South
Bothell, WA 98011

Re: K063620
Trade/Device Name: EKOS Micro Infusion System
Regulation Number: 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: II
Product Code: KRA
Dated: April 24, 2007
Received: April 25, 2007

Dear Ms. Kersten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of the EKOS Micro-Infusion system used for intracoronary thrombolytic therapy administration have not been established. In particular, the ultrasound energy delivered by the EKOS micro-infusion system is not intended to be therapeutic, and the safety and effectiveness of the EKOS system for coronary thrombolysis or thrombectomy (i.e., clot disruption) have not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.

Director

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

1.10 Indications for Use Statement

EKOS Corporation
11911 North Creek Parkway South
Bothell, WA 98011

Indications for Use Statement510(k) Number (if known): K063620Device Name: EKOS Micro-Infusion System*Indications for Use:*

The EKOS Micro-Infusion System is intended for regional infusion of contrast materials into selected vessels in the neurovasculature. The EKOS Micro- Infusion System may be used for controlled, regional infusion into selected vessels.

The EKOS Micro-Infusion system is intended to deliver physician specified fluids to the coronary vasculature.

WARNING: The safety and effectiveness of the EKOS Micro-Infusion system used for intracoronary thrombolytic therapy administration have not been established. In particular, the ultrasound energy delivered by the EKOS Micro-Infusion system is intended to be therapeutic, and the safety and effectiveness of the EKOS system for coronary thrombolysis or thrombectomy (i.e., clot disruption) have not been established.

Concurrence of CDRH, Office of Device Evaluation (ODE)Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



Division Sign-Off

8.0 510(k) Summary

K063620

Applicant Name: EKOS Corporation

AUG - 6 2007

Address: 11911 North Creek Parkway South
Bothell, WA 98011Contact Person: Jocelyn Kersten
Director, Regulatory AffairsTelephone: (425) 415-3132Fax: (425) 415-3102Device: EKOS Micro-Infusion SystemClassification: CFR 870.1210 – Continuous Flush CatheterPanel: CardiovascularProduct Code: KRAIntended Use:

The EKOS Micro-Infusion System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

The EKOS Micro-Infusion System is intended for regional infusion of contrast materials into selected vessels in the neurovasculature. The EKOS Micro- Infusion System may be used for controlled, regional infusion into selected vessels.

The EKOS Micro-Infusion system is intended to deliver physician specified fluids to the coronary vasculature.

Device Description: The EKOS Micro-Infusion System is an infusion catheter system designed to deliver fluids through the catheter end-hole while simultaneously delivering ultrasound energy via a transducer element at the distal catheter tip.

Predicate Basis: The EKOS Micro-Infusion System is substantially equivalent to other legally marketed devices. These devices include:

EKOS Micro-Infusion System, (EKOS Corporation, K053437, K053432, K062507, K062508)

Endeavor Infusion Catheter, (Cordis Corporation, K972110)

PV 0.018 F/X, (JoMed, K944004)

Renegade Hi-Flo Microcatheter, (Boston Scientific Corporation, K000177)

TurboTracker 18 Infusion Catheter, (Boston Scientific Corporation, K960806)

FasTracker 10 Infusion Catheter, (Boston Scientific Corporation, K926243)

Performance:

EKOS has conducted preclinical bench and animal studies with the Micro-Infusion System. These studies demonstrate that the performance of the Micro-Infusion System meets its design specifications and is safe and effective for its intended use.